

FORM PTO-1390 OFFICE (Modified)		U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK		ATTORNEY'S DOCKET NUMBER 32860-001072/US
TRANSMITTAL LETTER TO THE UNITED STATES DESIGNATED/ELECTED OFFICE (DO/EO/US) CONCERNING A FILING UNDER 35 U.S.C. 371				U.S. APPLICATION NO. (If known, see 37 CFR 1.5)
				NEW
				EXPRESS MAIL LABEL NO. <b>10/589562</b>
INTERNATIONAL APPLICATION NO.		INTERNATIONAL FILING DATE		PRIORITY DATE CLAIMED
PCT/EP2005/050401		January 31, 2005		February 18, 2004 October 28, 2004
<b>TITLE OF INVENTION</b> METHOD FOR VERIFYING THE FEASIBILITY OF A MEDICAL STUDY USING ACCEPTANCE CRITERIA FOR PATIENTS				
<b>APPLICANT(S) FOR DO/EO/US</b> Klaus ABRAHAM-FUCHS, Rainer KUTH, Dr. Eva RUMPEL, Markus SCHMIDT, Dr. Siegfried SCHNEIDER, Horst SCHREINER, and Dr. Gudrun ZAHLMANN				
Applicant herewith submits to the United States Designated/Elected Office (DO/EO/US) the following items and other information:				
<p>1. <input checked="" type="checkbox"/> This is a <b>FIRST</b> submission of items concerning a filing under 35 U.S.C. 371.</p> <p>2. <input type="checkbox"/> This is a <b>SECOND</b> or <b>SUBSEQUENT</b> submission of items concerning a filing under 35 U.S.C. 371.</p> <p>3. <input checked="" type="checkbox"/> This express request to begin national examination procedures (35 U.S.C. 371(f)) at any time rather than delay examination until the expiration of the applicable time limit set in 35 U.S.C. 371(b) and PCT Articles 22 and 39 (1).</p> <p>4. <input checked="" type="checkbox"/> The US has been elected by the expiration of 19 months from the priority date (Article 31).</p> <p>5. <input checked="" type="checkbox"/> A copy of the International Application as filed (35 U.S.C. 371(c)(2))           <ul style="list-style-type: none"> <li>a. <input checked="" type="checkbox"/> is transmitted herewith (required only if not transmitted by the International Bureau).</li> <li>b. <input checked="" type="checkbox"/> has been transmitted by the International Bureau.</li> <li>c. <input type="checkbox"/> is not required, as the application was filed in the United States Receiving Office (RO/US).</li> </ul> </p> <p>6. <input checked="" type="checkbox"/> An English language translation of the International Application as filed (35 U.S.C. 371(c)(2)).           <ul style="list-style-type: none"> <li>a. <input checked="" type="checkbox"/> is transmitted herewith.</li> <li>b. <input type="checkbox"/> has been previously submitted under 35 U.S.C. 154(d)(4)</li> </ul> </p> <p>7. <input checked="" type="checkbox"/> Amendments to the claims of the International Application under PCT Article 19 (35 U.S.C. 371(c)(3)).           <ul style="list-style-type: none"> <li>a. <input checked="" type="checkbox"/> are transmitted herewith (required only if not transmitted by the International Bureau).</li> <li>b. <input checked="" type="checkbox"/> have been transmitted by the International Bureau.</li> <li>c. <input type="checkbox"/> have not been made; however, the time limit for making such amendments has NOT expired.</li> <li>d. <input type="checkbox"/> have not been made and will not be made.</li> </ul> </p> <p>8. <input type="checkbox"/> An English language translation of the amendments to the claims under PCT Article 19 (35 U.S.C. 371(c)(3)).</p> <p>9. <input checked="" type="checkbox"/> An oath or declaration of the inventor(s) (35 U.S.C. 371(c)(4)).</p> <p>10. <input type="checkbox"/> An English language translation of the annexes of the International Preliminary Examination Report under PCT Article 36 (35 U.S.C. 371(c)(5)).</p>				
<b>Items 11. to 20. below concern document(s) or information included:</b>				
<p>11. <input checked="" type="checkbox"/> An Information Disclosure Statement under 37 CFR 1.97 and 1.98-1449, International Search Report (PCT/ISA/210 and PCT/ISA/220) in English and PTO Form 1449</p> <p>12. <input checked="" type="checkbox"/> An assignment document for recording. A separate cover sheet in compliance with 37 CFR 3.28 and 3.31 is included.</p> <p>13. <input checked="" type="checkbox"/> A <b>FIRST</b> preliminary amendment.</p> <p>14. <input type="checkbox"/> A <b>SECOND</b> or <b>SUBSEQUENT</b> preliminary amendment.</p> <p>15. <input checked="" type="checkbox"/> A substitute specification.</p> <p>16. <input type="checkbox"/> A change of power of attorney and/or address letter.</p> <p>17. <input type="checkbox"/> A computer-readable form of the sequence listing in accordance with PCT Rule 13ter.2 and 35 U.S.C. 1.821-1.825.</p> <p>18. <input type="checkbox"/> A second copy of the published international application under 35 U.S.C. 154(d)(4).</p> <p>19. <input type="checkbox"/> A second copy of the English language translation of the international application under 35 U.S.C. 154(d)(4).</p> <p>20. <input checked="" type="checkbox"/> Other items or information: Formal Drawing; Article 34 Amended Sheet; PCT/IPEA/416; PCT/ISA/237; PCT/IPEA/409</p>				

U.S. APPLICATION NO (if known, see 37 CFR 1.5)

10/589562

INTERNATIONAL APPLICATION NO  
PCT/EP2005/050401ATTORNEY'S DOCKET NUMBER  
32860-001072/US21.  The following fees are submitted:

## PCT FEES – NATIONAL STAGE:

<u>Fee Code</u>	<u>Description</u>	<u>Fee</u>
1631	Basic National Stage Fee.....	\$300.00
1632	National Stage Search Fee.....	\$400.00
1633	National Stage Examination Fee.....	\$200.00

CALCULATIONS PTO USE ONLY

## ENTER APPROPRIATE FEE AMOUNT =

\$ 900.00

Surcharge of \$130.00 for furnishing the oath or declaration later than  20  30 Months from the earliest claimed priority date (37 CFR 1.492(e)).

\$ —

PAGES	PAGES FILED	EXTRA PAGES FILED IN 50 PAGE SEGMENTS	RATE	
Total Pages	15 - 100 =0	0	X 250.00	\$ 0.00
CLAIMS	NUMBER FILED	NUMBER EXTRA	RATE	
Total Claims	12 - 20 =	0	X 50.00	\$ 0.00
Independent Claims	1 - 3 =	0	X 200.00	\$ 0.00
MULTIPLE DEPENDENT CLAIM(S) (if applicable)	_____	+ 360.00	\$ 0.00	
<b>TOTAL OF ABOVE CALCULATIONS =</b>				\$ 900.00
<input type="checkbox"/> Applicant claims small entity status. See 37 CFR 1.27. The fees indicated above are reduced by 1/2.				\$ —
<b>SUBTOTAL =</b>				\$ 900.00
Processing fee of \$130.00 for furnishing the English translation later than <input type="checkbox"/> 20 <input type="checkbox"/> 30 Months from the earliest claimed priority date (37 CFR 1.492(f)).				\$ —
<b>TOTAL NATIONAL FEE =</b>				\$ 900.00
Fee for recording the enclosed assignment (37 CFR 1.21(h)). The assignment must be accompanied by an appropriate cover sheet (37 CFR 3.28, 3.31). \$40.00 per property +				\$ 40.00
<b>TOTAL FEES ENCLOSED =</b>				\$ 940.00
	Amount to be: refunded			
	charged			

- a.  A check in the amount of \$940.00 to cover the above fees is enclosed.
- b.  Please charge my Deposit Account No. 08-0750 in the amount of \$ \_\_\_\_\_ to cover the above fees.  
A triplicate copy of this sheet is enclosed.
- c.  The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Deposit Account No. 08-0750.

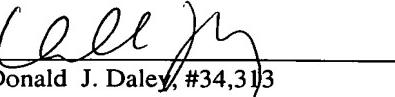
**NOTE: Where an appropriate time limit under 37 CFR 1.494 or 1.495 has not been met, a petition to revive (37 CFR 1.137(a) or (b)) must be filed and granted to restore the application to pending status.**

Send all correspondence to:

**Harness, Dickey & Pierce, P.L.C – Customer No. 30596  
Post Office Box 8910  
Reston, Virginia 20195**

Date: August 16, 2006

DJD:dpg

By   
Donald J. Daley, #34,313

10/589562  
IAP11 Rec'd PCT/PTO 16 AUG 2006

PATENT

IN THE U.S. PATENT AND TRADEMARK OFFICE

Applicant(s): Klaus ABRAHAM-FUCHS et al.  
Int'l Application No.: PCT/EP2005/050401  
Application No.: NEW APPLICATION  
Filed: August 16, 2006  
For: METHOD FOR VERIFYING THE FEASIBILITY OF A  
MEDICAL STUDY USING ACCEPTANCE CRITERIA FOR  
PATIENTS

LETTER

Customer Service Window  
Randolph Building  
401 Dulany Street  
Alexandria, VA 22314  
Mail Stop PCT

August 16, 2006

Sir:

Amended claims are attached hereto (which correspond to Article 34 amendments or to claims attached to the International Preliminary Examination Report), as required by 35 U.S.C. § 371(c)(3). The Article 34 amended claims are incorporated in the included substitute specification and Preliminary Amendment.

Respectfully submitted,

HARNESS, DICKEY & PIERCE, P.L.C.

By:   
Donald J. Daley, Reg. No. 34,313

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New Patent Claim 1

1. A method for verifying the feasibility of a medical project with acceptance criteria (4) for patients, having the following steps:

- target criteria (6) are set for the project,
- a patient group (17) comprising potential patients is selected with the aid of the acceptance criteria (4) from a database (10) containing patient data (14) of patients,
- the patient data (14) of the patient group (17) are evaluated with the aid of the target criteria (6) and a measure (21) of the feasibility of the project is calculated.